IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

ROZLYN ACKERMANN, Individually and as Personal Representative of the Estate of MARTIN LINDSEY ACKERMANN, Deceased, Plaintiff,	)	
vs.	)	CIVIL ACTION NO. 4-05-cv-0084-MHS-DDB
WYETH PHARMACEUTICALS, Defendant.	)	

MEMORANDUM IN SUPPORT OF DEFENDANT'S
MOTION FOR SUMMARY JUDGMENT (STATE LAW)

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I. INTRODUCTION

Plaintiff's complaint rests largely on the claim that Wyeth failed to warn of the purported risk that its prescription antidepressant, Effexor, could cause depressed adults to commit suicide. To prevail on these claims, plaintiff must show that Martin Ackermann committed suicide because Wyeth failed to adequately warn his prescribing physician, Dr. Thomas Sonn. But Dr. Sonn knew of the purported suicide risk when he saw Martin Ackermann in January 2002. Moreover, even with Dr. Sonn's knowledge of Martin Ackermann's suicide and changes to antidepressant warnings made after that date, Dr. Sonn would still prescribe Effexor to, and communicate with, the Ackermanns today just as he did in January 2002. Because additional warnings would not have changed Dr. Sonn's conduct, the learned intermediary doctrine bars plaintiff's failure to warn claims.

Plaintiff's other claims fare no better. Her warranty claims fail because the seven Effexor pills Martin Ackermann took were from a free sample pack. Thus, there was no purchase or sale, as warranty law requires. Her express warranty claims fail for the additional reason that there is no evidence that Wyeth made suicide-related warranties. Her Texas Deceptive Trade Practices-Consumer Protection Act ("DTPA") claims fail because (a) there was no actual or intended Effexor "purchase" that would make Martin Ackermann a "consumer" under the DTPA, and (b) statutory DTPA claims do not survive death. Finally, plaintiff's fraud and misrepresentation claims fail because plaintiff cannot establish that Wyeth made (or that Martin Ackermann or Dr. Sonn relied upon) suicide-related misrepresentations.

II. STATEMENT OF MATERIAL FACTS

1. On November 12, 2001, Martin Ackermann and his wife, plaintiff Rozlyn Ackermann, saw Dr. Carolyn Terry, an internist. Dr. Terry prescribed Celexa, a

prescription antidepressant, for Martin Ackermann. (Medical Specialists Assoc. Records re: Martin Ackermann ("Med. Spec. Records") at 00023 (Ex. A)).

2. Martin Ackermann filled the Celexa prescription the same day and obtained thirty 20 mg. pills. (CVS Pharmacy Record at 00001(Ex. B)).

3. Non-party Forest Laboratories makes Celexa, which is a selective serotonin reuptake inhibitor ("SSRI") available in 10 mg., 20 mg., and 40 mg. pills. (*See* Complaint at 1).

4. On November 19, 2001, Martin Ackermann saw Dr. Martin Cohen, his long-time internist. Dr. Cohen's notes reflect that Martin Ackermann was "doing better on his Celexa 20 mg and is somewhat calmer. He still has a way to go. I will see him back in three weeks, but he has settled down enough to function better ... Continue Rx." (Med. Spec. Records at 00024 (Ex. A)).

5. By December 4, 2001, Martin Ackermann "ha[d] not yet contacted [a] psychologist, but needs to. Recommendations given." (*Id.*). Dr. Terry's notes also state that Martin Ackermann was provided with a second Celexa prescription but at a higher, 40 mg. dose (*i.e.*, the recommended full-strength dose). (*Id.* at 00024-25).

6. Martin Ackermann filled the Celexa prescription the same day and obtained thirty 40 mg. Celexa pills. (CVS Pharmacy Record at 00001 (Ex. B)).

7. On December 17, 2001, Dr. Terry provided Martin Ackermann with a third Celexa prescription for his depression at the higher, 40 mg. dose. (Med. Spec. Records at 00025 (Ex. A)).

8. Martin Ackermann filled that prescription on December 27, 2001, obtaining another thirty 40 mg. Celexa pills. (CVS Pharmacy Record at 00001 (Ex. B)).

9. On January 4, 2002, Martin and Rozlyn Ackermann saw Dr. Thomas Sonn, a psychiatrist, seeking treatment for Martin Ackermann's depression. (*See* 12/19/05 Dr. Thomas Sonn Deposition Transcript ("Sonn Dep.") at 63:17-23 (Ex. C); Calendar of Dr. Thomas Sonn ("Sonn Calendar") (Ex. D)).

10. At an appointment the following day, Dr. Sonn gave Martin Ackermann a free, fourteen-pill sample pack of Effexor that a Wyeth sales representative had left at Dr. Sonn's offices without charge. (Sonn Dep. at 112:3-5, 112:22 - 113:8, 191:17-22 (Ex. C); 12/22/05 Rozlyn Ackermann Deposition Transcript ("R. Ackermann Dep.") at 98:25 - 99:10 (Ex. E); Pl's Resp. Int. No. 8 (Ex. F)).

11. Effexor is a prescription antidepressant that acts as a selective serotonin and norepinephrine reuptake inhibitor ("SNRI"), but has an SSRI effect, particularly at lower doses.[1] (*See* Complaint at ¶ 5; 6/5/01 Effexor XR Package Insert at 3 (Ex. G)).

12. Before January 2002, the FDA had reviewed and approved the warnings and information printed on the package insert that accompanied Effexor. (5/2/01 Letter from Russell Katz, M.D. (FDA) (Ex. H); 6/5/01 Effexor XR Package Insert (Ex. G)).

13. The sample pack Dr. Sonn gave Martin Ackermann was labeled "Sample - Not For Sale" on both the box and the pill blister-pack inside the box. (Pictures of Martin Ackermann's Effexor XR Sample/Blister Packs ("Effexor Pack Pictures") at 3, 5 (Ex. I) (pictures of Martin Ackermann's Effexor sample box and pill blister-pack)).

14. The sample pack that Dr. Sonn gave Martin Ackermann was the only Effexor that Martin Ackermann obtained. (R. Ackermann Dep. at 98:25 - 99:10 (Ex. E);

[1] Effexor is available in either an immediate release formula, Effexor, or an extended release formula, Effexor XR. Martin Ackermann took Effexor XR, but the differences between Effexor and Effexor XR are not material to this motion. Accordingly, Effexor XR will be referred to simply as "Effexor."

Sonn Dep. at 112:3-5 (Ex. C); *see also* CVS Pharmacy Record at 00001 (Ex. B) (Martin Ackermann's pharmacy record that does not list Effexor)).

15. Martin Ackermann "did not seem to have read anything or know anything about Effexor" before it was given to him, and Dr. Sonn did not recall meeting an Effexor sales representative before January 2002. (Sonn Dep. at 110:9-11, 196:7-11 (Ex. C)).

16. The Ackermanns relied on Dr. Sonn to select their antidepressant and provide them with warnings. Rozlyn Ackermann had not heard of or seen advertisements for Effexor before January 2002 and did not review the package insert, and the Ackermanns may not have had a copy of the package insert. (R. Ackermann Dep. at 145:24 - 146:14; 147:18 - 148:9 (Ex. E)).

17. Martin Ackermann took only seven Effexor pills – one 37.5 mg. pill each day from January 6 through January 8, 2002 and one 75 mg. pill each day from January 9 through January 12, 2002. (R. Ackermann Dep. at 96:12-15 (Ex. E); Effexor Pack Pictures at 3 (Ex. I) (picture of Martin Ackermann's blister-pack with 7 of 14 pills gone)). For treating depression, the recommended therapeutic doses of Effexor ranged from 75 mg. to 225 mg. (6/5/01 Effexor XR Package Insert at 12 (Ex. G)).

18. In early January 2002, the Ackermanns saw Dr. Sonn four times in nine days – January 4, 5, 9, and 12. (Sonn Dep. at 66:7-12 (Ex. C); Sonn Calendar (Ex. D)).

19. At the last appointment with Dr. Sonn on January 12, 2002, Martin Ackermann complained that Effexor was affecting "his manhood" and said that he no longer would take the drug. (Sonn Dep. at 131:24 - 132:9, 133:5-11 (Ex. C)).

20. At that same appointment, Martin Ackermann refused to continue treatment with Dr. Sonn and, although Dr. Sonn told him he "needed a doctor" and

"offered him names," there is no evidence that Martin Ackermann ever saw another health professional. (*Id.* at 139:3-16).

21. After Martin Ackermann took his final Effexor pill on January 12, he resumed taking Celexa. (R. Ackermann Dep. at 92:19-23, 148:10-13 (Ex. E)).

22. Martin Ackermann committed suicide on January 17, 2002 – five days after he last took Effexor. (Complaint at ¶ 11; R. Ackermann Dep. at 96:12-15 (Ex. E)).

23. The post-mortem analysis of Martin Ackermann's blood detected Celexa at levels consistent with a therapeutic dose, but detected no Effexor. (6/13/06 Edward J. Barbieri, Ph.D. Deposition Transcript at 37:5-13, 68:15 – 69:1, 123:4 – 124:14, 128:21 – 129:17 (Ex. J); *see also* Medical Examiner's Report at 00004, 00029 (Ex. K) (medical examiner's report and lab report showing "citalopram" (*i.e.*, Celexa), but not Effexor)).

24. The January 17, 2002 police report states that Martin Ackermann "had been taking Selexis [sic – Celexa] and [Rozlyn Ackermann] thought the medication had caused him to talk strangely," and the emergency department record lists Celexa as the only "Current Medication[]." (Plano Police Report at 00009 (Ex. L); Medical Center of Plano Records at 00007 (Ex. M); *see also* R. Ackermann Dep. 112:19 - 113:2 (Ex. E)).

25. In January 2002, the Effexor package insert included the precaution:

> *Suicide*
> The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy. Prescriptions for Effexor XR should be written for the smallest quantity of capsules consistent with good patient management in order to reduce the risk of overdose.

(6/5/01 Effexor XR Package Insert at 6 (Ex. G)).

26. The Effexor package insert also (a) reported that (and gave information about the frequency at which) patients in clinical trials had experienced "agitation,"

"intentional injury," "suicide attempt," "hostility," "manic reaction," "paranoid reaction," "psychosis," "akathisia," "akinisia," and "suicidal ideation;" (b) recommended that patients discontinuing Effexor be tapered off the drug; and (c) identified many discontinuation symptoms that had been reported. (*Id.* at 8-11, 13 (Ex. G)).

27. When Dr. Sonn treated Martin Ackermann, he (a) reviewed the Effexor package insert that was reproduced in the *Physicians' Desk Reference* (Sonn Dep. at 42:11 - 43:25 (Ex. C)); (b) was aware that depressed patients have a heightened risk of suicide (*id.* at 18:16-19, 28:4-12, 28:15-19); (c) was aware of the need to monitor depressed patients for suicidal thinking and monitored Martin Ackermann for that purpose (*id.* at 32:10-14, 34:3-5); (d) was aware of claims that Effexor might be causally related to suicide or suicidality and considered those risks in treating Martin Ackermann (*id.* at 38:9-18); (e) chose (and still chooses) not to discuss suicide-related risks with patients directly because mentioning suicide might prompt suicidal thinking or cause patients to stop treatment (*id.* at 117:20-22, 119:20 - 120:20, 121:21-25); (f) was aware that some Effexor patients attempt suicide, have suicidal ideation, and experience agitation or akathisia, but saw no signs of those in Martin Ackermann (*id.* at 41:2-8, 44:1-7, 44:12, 45:7-15, 48:6-9, 98:23-25, 133:12-14, 136:14-18; 150:18-22); (g) was aware that patients who have taken large doses of Effexor for substantial periods of time may need to be tapered off Effexor (*id.* at 25:20-25, 147:1-3); and (h) saw no need to taper Martin Ackermann off Effexor because he had taken only a low dose for a short period of time (*id.* at 145:17-146:2, 148:4-10).

28. Despite his current knowledge of Martin Ackermann's suicide and changes to antidepressant warnings made since January 2002, Dr. Sonn (a) still believes

Effexor's January 2002 package insert gave adequate warnings about the drug's suicide-related risks (*id.* at 53:22 - 54:2, 116:5-8); (b) would prescribe Effexor to Martin Ackermann today (*id.* at 157:10-13); (c) would take the same approach to warnings that he did with the Ackermanns in January 2002 (*id.* at 127:16-19; 130:5-8; 157:2-7; 187:11-19; 188:7-20); and (d) believes Effexor's benefits outweigh its risks (*id.* at 20:23 - 21:2).

III. SUMMARY JUDGMENT STANDARD

Summary judgment "shall be rendered forthwith" when "there is no genuine issue as to any material fact and ... the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). "A 'dispute about a material fact is "genuine" ... if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.' Therefore, summary judgment is appropriate if the nonmovant fails to establish facts supporting an essential element of her prima facie claim. In making the determination of whether summary judgment [i]s proper, the Court reviews the facts, and all inferences drawn from those facts, in the light most favorable to the party opposing the motion." *Cutrera v. Board of Supervisors*, 429 F.3d 108, 110 (5th Cir. 2005) (citations omitted).

IV. WYETH IS ENTITLED TO SUMMARY JUDGMENT

Plaintiff's warnings-based claims fail due to both the learned intermediary doctrine and Texas Civil Practice and Remedies Code ("TCPRC") § 82.007.[2] Plaintiff's warranty and Texas Deceptive Trade Practices-Consumer Protection Act claims fail because, among other things, Martin Ackermann took Effexor from a free sample pack and, thus, there was no "sale." Plaintiff's misrepresentation and fraud claims fail because plaintiff cannot establish either that Wyeth made misrepresentations to Dr. Sonn or

[2] In this diversity action, Texas choice-of-law rules apply. Martin Ackermann lived in Texas and was prescribed, obtained, ingested, and allegedly injured by Effexor there. Accordingly, Texas substantive law applies. *See Primrose Operating Co. v. National Am. Ins. Co.*, 382 F.3d 546, 552 n.4 (5th Cir. 2004).

Martin Ackermann or that they relied on any representation by Wyeth. Accordingly, Wyeth is entitled to summary judgment.

A. Plaintiff's Warnings Claims Should Be Dismissed Under The Learned Intermediary Doctrine and Tex. Civ. Prac. & Rem. Code § 82.007.

Although she relies upon several different legal theories – strict liability, negligence, and implied warranty – plaintiff's complaint rests primarily on allegations that Effexor's suicide-related warnings were inadequate.[3] (*See* Complaint at ¶¶ 7-10, 15, 17, 18). All these warnings-based claims are barred by both the learned intermediary doctrine and TCPRC § 82.007.

1. The Learned Intermediary Doctrine Bars Plaintiff's Warnings Claims.

"The learned intermediary doctrine applies in medical products liability actions in Texas." *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) (citation omitted). It "applies to all causes of action, including strict liability and DTPA violations, based on a failure to warn." *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 740 (N.D. Tex. 2000) (applying Texas law) (citations omitted); *accord In re Norplant Contraceptive Prods. Liab. Litig.*, 165 F.3d 374, 378 (5th Cir. 1999) (applying doctrine to DTPA claims).

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[3] Plaintiff's complaint does not allege design or manufacturing defect claims, and plaintiff's interrogatory responses confirm that she is not pursuing those claims. (Pl's Resp. Int. Nos. 24, 25 (Ex. O)). Plaintiff's "marketing defect," "failure to test," "failure to implement appropriate patient screening mechanisms," "over-promotion," and breach of implied warranty claims (Complaint at ¶¶ 17-19) are all failure-to-warn claims – **Marketing Defect**: *Caterpillar Inc. v. Shears*, 911 S.W.2d 379, 382 (Tex. 1995) (a "failure to warn of a product's potential dangers when warnings are required is a type of marketing defect") (citation omitted); **Failure to Test**: *American Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997) ("negligent testing claims [were] inextricably intertwined with ... negligent failure to warn claim"); *Pennington v. Vistron Corp.*, 876 F.2d 414, 420 (5th Cir. 1989) (applying Louisiana law; failure to test claim was "not actionable per se, but instead is a variation of the failure to warn theory"); **Overpromotion**: *Dusek v. Pfizer, Inc.*, H-02-3559, 2004 U.S. Dist. LEXIS 28049, slip op. at *7 (S.D. Tex. Nov. 22, 2004) (FDA approval of warnings preempted negligent overpromotion claims); *Caraker v. Sandoz Pharms. Co.*, 172 F. Supp. 2d 1018, 1030 (N.D. Ill. 2001) (applying Illinois law; "overpromotion ... allegation does not constitute a tort distinct from the inadequate warnings tort"); **Implied Warranty**: *Stewart v. Transit Mix Concrete & Materials Co.*, 988 S.W.2d 252, 255 (Tex. App. - Texarkana 1998, pet. denied) (implied warranty claim required showing that "failure to adequately warn was a proximate cause of [his] injuries") (footnote omitted). Wyeth has not located Texas authority recognizing an "inappropriate patient screening" claim against a prescription drug manufacturer, although, if such a claim exists, it would be a warnings claim.

The learned intermediary doctrine's rationale "'is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy. The duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances.'" *Humble Sand & Gravel, Inc. v. Gomez*, 146 S.W.3d 170, 191 n.52 (Tex. 2004) (citation omitted). "[T]o recover for a failure to warn under the learned intermediary doctrine, a plaintiff must show: (1) the warning was defective; and (2) the failure to warn was a producing cause of the plaintiff's condition or injury." *Porterfield*, 183 F.3d at 468 (citation omitted). Here, plaintiff cannot make either required showing; her warnings claims are barred.

a. Plaintiff cannot establish that the warnings were defective.

"[W]hen a warning specifically mentions the circumstances complained of, it is adequate as a matter of law." *McNeil v. Wyeth*, No. 3-02-CV-2072-L, 2005 U.S. Dist. LEXIS 3477, slip op. at *14 (N.D. Tex. Mar. 4, 2005)), *appeal docketed*, No. 10509 (5th Cir. Mar. 30, 2005); *accord Gerber v. Hoffmann-La Roche, Inc.*, 392 F. Supp. 2d 907, 916 (S.D. Tex. 2005) (same). Thus, *McNeil* found that a package insert that disclosed the risk that a drug might cause a condition was adequate as a matter of law notwithstanding a claim that the insert should have quantified the specific risks of long-term exposure. 2005 U.S. Dist. LEXIS 3477, slip op. at *18. Similarly, *Gerber* found a warning discussing the risks of birth defects to be legally adequate even though, after the plaintiff took the drug, the manufacturer provided stronger, "black box" warnings. 392 F. Supp. 2d at 919. And *Brumley v. Pfizer, Inc.*, 149 F. Supp. 2d 305 (S.D. Tex. 2001), found that a warning in the package insert's "precautions" section was adequate as a matter of law despite claims it should have been in the "warnings" section. *Id.* at 311.

Here, plaintiff alleges that Wyeth should have warned "about the increased risk of suicide, and it[s] precursor conditions, for patients taking Effexor, particularly during the early phases of therapy" and the supposed need for a "'wash-out' period of five half lives" for patients who "switch[ed] from one serotonergic drug to another." (Pl's Resp. Int. No. 22 (Ex. O)). Yet the Effexor package insert at the time Martin Ackermann took the drug was adequate as a matter of law because, as in *McNeil*, *Gerber*, and *Brumley*, it "specifically mention[ed] the circumstances complained of."

Effexor's package insert included a precaution about both the risk of suicide and the need to be particularly vigilant early in treatment:

> *Suicide*
> The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy. Prescriptions for Effexor XR should be written for the smallest quantity of capsules consistent with good patient management in order to reduce the risk of overdose.

(6/5/01 Effexor XR Package Insert at 6 (Ex. G)). It also reported that patients in clinical trials reported "intentional injury," suicide attempt," and "suicidal ideation," as well as plaintiff's alleged "precursor conditions" – "agitation," "hostility," "manic reaction," "paranoid reaction," "psychosis," "akathisia," and "akinisia."[4] (*Id.* at 8, 11). Further, it recommended that patients who discontinue Effexor be tapered off the drug and identified many discontinuation symptoms that had been reported. (*Id.* at 13).

The legal adequacy of the suicide-related warnings on the Effexor package insert as of the time of Martin Ackermann's death is reinforced by the fact that the FDA, which

[4] The package insert also reported the frequency with which patients experienced these conditions. (6/5/01 Effexor XR Package Insert at 8, 11 (Ex. G)). The percentages of Effexor-treated and placebo-treated patients who experienced "agitation" were reported in Table 2. (*Id.* at 8). The other conditions were grouped into categories that defined their frequency, either "infrequent" (*i.e.*, events that occurred in 1/100 to 1/1000 patients) or "rare" (*i.e.*, events that occurred in fewer than 1/1000 patients). (*Id.* at 11).

had studied modern antidepressants' suicide-related risks for years, reviewed and approved the insert. (*See* 5/2/01 Letter Russell Katz, M.D. (FDA) (Ex. H)). Indeed, "in FDA's judgment there was not reasonable evidence" in early 2002 of an association between antidepressant use and suicidality and, accordingly, warnings to that effect "would have been false or misleading, and thus contrary to federal law." (*See* U.S. *Amicus* Brief in *Kallas v. Pfizer, Inc.* at 2-3 (Ex. P)).

Moreover, the prescribing physician here, Dr. Thomas Sonn, believes that the suicide-related and other warnings provided with Effexor in early 2002 were adequate:

> Q. Based on your review that you've done in the past and – and that you did today of the warning labeling for Effexor, did you believe that you were adequately warned about the risks associated with the drug before prescribing it for Mr. Ackermann?
>
> A. Yes.

(Sonn Dep. at 53:1 - 54:2 (Ex. C); *see also id.* at 116:5-8 ("Q. Did you feel as ... though you were adequately informed about those risks of [possible side effects for] Effexor before going in to treat Mr. Ackermann? A. Yes.")).

b. Plaintiff cannot establish that allegedly inadequate warnings were a "producing cause."

Courts applying Texas law have outlined two situations where, under the learned intermediary doctrine, supposed warning defects are not a "producing cause."[5] First, "[i]f the physician was aware of the possible risks involved in the use of the product but decided to use it anyway, the adequacy of the warning is not a producing cause of the

[5] Strict liability and DTPA claims require producing cause, while negligence and implied warranty claims require proximate cause. *Union Pump Co. v. Allbritton*, 898 S.W.2d 773, 775 (Tex. 1995) ("[n]egligence requires a showing of proximate cause, while producing cause is the test in strict liability"); *Purina Mills Co. v. Odell*, 948 S.W.2d 927, 935 (Tex. App. - Texarkana 1997, writ denied) (implied warranty claims require proximate cause); Tex. Bus. & Com. Code § 17.50(a) (DTPA claims require "producing cause"). Differences between the two are immaterial here because "[c]ommon to both proximate and producing cause is causation in fact, including the requirement that the defendant's conduct or product be a substantial factor in bringing about the plaintiff's injuries." *Union Pump*, 898 S.W.2d at 775 (citation omitted).

injury." *Porterfield*, 183 F.3d at 468 (citations omitted). Second, and "[e]ven if the physician [wa]s not aware of a risk, 'the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating physician would not have used or prescribed the product.'" *Dyer*, 115 F. Supp. 2d at 732 (citations omitted). Both situations require a plaintiff to show "that a proper warning would have changed the decision of the intermediary to prescribe the product." *Brumley*, 149 F. Supp. 2d at 313 (citations omitted); *accord Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 95 (Tex. App. - Texarkana 2000, no pet.). Plaintiff cannot make that showing.

Dr. Sonn was aware of Effexor's risks, yet "use[d] it anyway" because he believed the potential benefits outweighed the potential risks. (Sonn Dep. at 20:23 - 21:2 (Ex. C) ("Q. [H]ave you concluded for your patients that you've prescribed Effexor that the ... benefits have[] outweighed the risks? A. Oh, yes.")). When Dr. Sonn prescribed Martin Ackermann's Effexor, he –

> **Was aware that depressed patients have a heightened suicide risk.** (Sonn Dep. at 18:16-19 ("Q. And in your experience if depression is untreated or ineffectively treated, can that lead to suicide in certain circumstances? A. Yes."); *id.* at 28:4-12, 15-19 ("Q. [I]n terms of your general awareness of risk factors, in terms of your experience [and] reading, is it your understanding that suicide is an inherent risk of depression? A. Oh, certainly. Q. .... And how have you come to that understanding? A. Well, through life experience ... certainly in my training.... [Y]our main task is if you have a serious depression is to keep them alive.")).
>
> **Was aware of the need to monitor depressed patients for suicidal thinking and monitored Martin Ackermann for that purpose.** (*Id.* at 32:10-14, 34:3-5 ("Q. Given that ... suicide is inherent in depression as you stated, do you monitor for suicide when you're treating patients with antidepressant drugs? A. Yes.... Q. And the monitoring approach that you just described [for suicide in depressed patients], you took that approach with Mr. Ackermann? A. Yes.")).
>
> **Was aware of claims that Effexor might be causally related to suicide or suicidality and considered those possible risks in treating Martin**

Ackermann. (*Id.* at 38:9-18 ("Q. Based on your knowledge and experience then, ... by the time your were prescribing Effexor for Mr. Ackermann, is it fair to say that you were aware that there was an ongoing discussion about whether the antidepressant drugs could have some causative effect related to suicide or suicidality? A. ... Yes. Q. And ... is that a risk that you considered when prescribing these drugs? A. You have to.")).

Chose not to directly raise suicide-related risks with his patients due to his concern that it could prompt suicidal thinking or cause patients to stop treatment. (*Id.* at 117:20-22 ("A. [T]o say to somebody, 'This could make you suicidal,' would not ... be an appropriate thing."); *id.* at 119:20 - 120:10 ("Q. Do you have any concern that if ... you warn about some of these things, like suicide or suicidal ideation, that may discourage the depressed patient from using the drugs? A. Well, it might if you ... put it in those stark terms ... [T]hat's just not the best way to do it in my opinion .... But ... that's not to mean at all just because you don't use those words that you're not sensitive or aware or trying to gather information, dosing appropriately and all the things that ... make for good practice."); *id.* at 121:21-25 ("Q. And your practice was not to specifically warn about suicide or suicidal ideation? A. Yeah. Not ... specifically in those terms, no.")).

Was aware that some Effexor patients attempt suicide, have suicidal ideation, and experience plaintiff's alleged "precursor conditions" – agitation or akathisia – but saw no signs of them in Martin Ackermann.[6] (*Id.* at 150:18-22 ("Q. You mentioned several times in your statement about suicide and suicidality , and ... your conclusion that you didn't think Mr. Ackermann was suicidal during your treatment? A. That's correct."); *id.* at 109:25 - 110:1 ("A. [W]hen he left my office on January 12th, he was not ... suicidal."); *id.* at 98:23-25 ("Q. And when you treated him then, you never saw any agitation on his part, physical agitation? A. No, not really."); *id.* at 136:14-18 ("Q. [D]id you observe any symptoms of a[k]athisia with Mr. Ackermann? A. No. Q. Did he complain of any? A. No."); *id.* at 133:12-14 ("Q. Did he [Martin Ackermann] voice any other complaints ... about Effexor other than sexual side effects? A. No.")).

Was aware that patients who have taken large doses of Effexor for a substantial period of time may need to be tapered off Effexor. (*Id.* at 25:20-25 ("A. [I]f patients are on Effexor and particularly ... if they've been at ... a higher dose and for a longer period of time, then you would ... taper them off of it"); *id.*

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[6] **Suicide Attempt** - Sonn Dep. at 44:1-7, 12 (Ex. C) ("Q. In terms of other side effects, ... were you aware that suicide attempts have been seen on patients who were taking antidepressant drugs, including Effexor? A. Oh, yeah. Yes. Q. You were aware of that before you prescribed for Mr. Ackermann? .... A. Oh, yes."); **Suicidal Ideation** - *id.* at 45:7-15 ("Q. And I take it ... that you were also aware that patients on SSRIs, including Effexor, have been reported to have suicidal ideations? A. Uh-huh. Q. And you were aware of that before you prescribed for Mr. Ackermann? .... A. Yeah. Yes."); **Agitation** - *id.* at 41:2-8 ("Q. In terms of agitation as a possible side effect of the drug [Effexor], I take it from your discretion [sic - description] before, you knew that that was a possible side effect going into prescribing for Mr. Ackermann – ? A. Uh-huh."); **Akathisia** - *id.* at 48:6-9 ("Q. Were you aware of ... a[k]athisia as a possible side effect before prescribing for Mr. Ackermann? A. Yeah.").

at 147:1-3 ("Q. [Y]ou were ... aware that there's a potential need for tapering of Effexor in certain circumstances? A. Yes.").

Saw no need to taper Martin Ackermann off Effexor because of his low dose and short time on the drug. (*Id.* at 145:24 - 146:2 ("A. [I]n view of the fact that he ... had taken such a small amount for such a short period of time, I didn't think that [discontinuing Effexor without tapering] was something that was likely to cause him difficulty."); *id.* at 148:4-10 ("A. [H]e would not have been receptive [to tapering]. He's somebody who said, 'This is it. I'm cutting this off.' And then if you had reason, like if you had taken a lot over a long period of time, maybe he would have taken that into account, to taper, but there was no – I didn't see a reason [to taper Mr. Ackermann off Effexor] and Mr. Ackermann had stopped it on his own.")).

In short, when he prescribed Effexor for Martin Ackermann, Dr. Sonn was aware of the risks that underlie plaintiff's warnings claim and nonetheless prescribed the drug because he believed it was, on balance, likely to be beneficial. Because he was "aware of the possible risks involved in the use of the product but decided to use it anyway," *Porterfield*, 183 F.3d at 468, plaintiff cannot establish causation.

But even if plaintiff could establish that Dr. Sonn was unaware of the relevant risks when he prescribed Effexor for Martin Ackermann (and she cannot), she still cannot establish that, if Wyeth had provided the warnings plaintiff alleges should have been given, he "would not have used or prescribed the product." *Dyer*, 115 F. Supp. 2d at 732. Notwithstanding his knowledge of, among other things, Martin Ackermann's suicide and changes in antidepressant warnings made since January 2002, Dr. Sonn testified that:

> Q. In terms of approach and Mr. Ackermann, if – if you were going to give him, if you could, Effexor today, would you have taken the same approach to warnings today that you did back then?
>
> A. Yes....
>
> Q. And in terms of the present knowledge and everything else, would you have prescribed Effexor for Mr. Ackermann if he were present today?
>
> A. Yes, I would.

(Sonn Dep. at 157:3-13 (Ex. C); *see also id.* at 127:16-19 ("Q. [T]oday if you had somebody – an adult patient newly on Effexor, would you give any different warning than what you had done in the past? A. I wouldn't feel [it was] medically ... indicated."); *id.* at 130:5-8 ("Q. [Y]ou would give essentially the same warning to Mr. Ackermann today if you were prescribing Effexor as you did back then? A. Yes.")).

On cross-examination, Dr. Sonn confirmed that, rather than risk being suggestive by discussing suicide with depressed – and, therefore, potentially suicidal – patients and their families, his practice remains to monitor depressed patients carefully for any signs of change, including any signs that might suggest suicidal tendencies:

> Q. Do you think a way to warn patients about this association [from a recent FDA public health advisory relating to antidepressants] that we're discussing right now would be [to] alert them to the fact that in some patients that these drugs have been reported to cause self-harm? Do you think that would be a fair way to alert them? ....
>
> A. I would have to say ... no....
>
> Q. Would you – in providing and prescribing Effexor for the first time today, given the black box warning from August of 2003 [sic] and given the public ... health advisory from July of this year, would you alert her [Mrs. Ackermann] to the fact that in some patients there are warnings about self-harm?
>
> A. If it were necessary to talk to her, I would tell her the same thing that I would tell the patient and to enlist their cooperation and reporting to me anything that concerned them. And this, I think – I can't speak for everybody, but the physicians I have spoken to still do not say [to patients] that this drug can lead to suicide, [they] try to ... warn people to acknowledge something without scaring them.

(*Id.* at 187:11-19, 188:7-20).

Different or additional warnings would not have changed Dr. Sonn's decisions to prescribe Effexor for Martin Ackermann and to advise the Ackermanns as he did about its risks. Thus, the learned intermediary doctrine's causation requirement bars plaintiff's

warnings claims, because she cannot establish that different or additional warnings "would have changed the decision of the intermediary to prescribe the product." *Brumley*, 149 F. Supp. 2d at 313 (citations omitted).

2. TCPRC § 82.007 Bars Plaintiff's Warnings Claims.

Texas Civil Practice and Remedies Code § 82.007(a) provides that, in product liability actions involving prescription drugs, "there is a rebuttable presumption" that the manufacturer is "not liable with respect to the allegations involving failure to provide adequate warnings" when the FDA approved the "warnings or information that accompanied the product."[7] Here, the FDA had approved Effexor's package insert before Martin Ackermann took the drug. (*See, e.g.*, 5/2/01 Letter from Russell Katz, M.D. (FDA) (Ex. H); 6/5/01 Effexor XR Package Insert (Ex. G)). Thus, TCPRC § 82.007(a) applies, and there is a presumption that Wyeth is "not liable" with respect to plaintiff's failure-to-warn claims.

TCPRC § 82.007(b) sets forth the five ways § 82.007(a)'s presumption may be rebutted.[8] Plaintiff seeks to proceed under TCPRC § 82.007(b)(1) (*see* Complaint at ¶ 12), which requires a plaintiff to establish that "the defendant ... withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury." That provision, however, does not apply because (a) it is preempted by federal law; and (b) plaintiff cannot make the showing it requires. Thus,

[7] TCPRC § 82.007 applies to this and other actions filed after July 1, 2003.

[8] In addition to TCPRC § 82.007(b)(1), which is discussed in the text, § 82.007(a)'s presumption may be rebutted if (a) the product was sold after the FDA ordered it removed from the market; (b) the product was promoted, sold, and used for an indication that was not FDA-approved; (c) the product was prescribed for an indication that was not FDA-approved; or (d) the defendant's violation of a federal anti-bribery statute caused the warnings to be inadequate. TCPRC § 82.007(b)(2) - (5). None of these provisions applies here.

because there is not "sufficient evidence contradicting the presumption [in TCPRC § 82.007(a)], the presumption is conclusive-determinative of the issue" of liability. Michael S. Hull, *et al.*, "House Bill 4 and Proposition 12: An Analysis with Legislative History, Part Two," 36 *Tex. Tech. L. Rev.* 51, 124 (2005).

a. TCPRC § 82.007(b)(1)'s "rebuttal provision" is preempted.

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001), the Supreme Court found that "State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with [its] judgment and objectives." Those claims "would ... cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, w[ould] later be judged insufficient in state court." *Id.* at 351. "[T]his sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted." *Id.* at 353.

TCPRC § 82.007(b)(1) permits TCPRC § 82.007(a)'s presumption of no liability to be rebutted by establishing a "fraud-on-the-FDA claim" – that a drug manufacturer either "withheld from or misrepresented to" the FDA information that was "material and relevant" and "causally related to the claimant's injury." Three courts have considered the extent to which federal law preempts nearly identical requirements in other states' laws. All three (a) found that, under *Buckman*, federal law preempted "rebuttal provisions" similar to TCPRC § 82.007(b)(1); (b) severed the "rebuttal provisions;" and (c) applied statutory liability limitations that were analogous to TCPRC § 82.007(a).

Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961, 965-66 (6th Cir. 2004), and *Henderson v. Merck & Co.*, No. 04-CV-05987, 2005 WL 2600220 (E.D. Pa. Oct. 11, 2005), *reconsid. denied*, 2005 WL 2864752 (E.D. Pa. Oct. 31, 2005), both involved a Michigan statute that provides that FDA-approved drugs are "not defective or

unreasonably dangerous," but the statute "does not apply" when one of several express exceptions is satisfied. Mich. Comp. Laws § 600.2946(5).[9] The relevant exception, subsection (a), says that the statutory bar to liability "does not apply" when the drug manufacturer "[i]ntentionally withholds from or misrepresents to" the FDA "required" information about the drug. *Id.* at § 600.2946(5)(a).

The Sixth Circuit found that plaintiffs attempting to invoke subsection (a) were asserting state law, fraud-on-the-FDA claims. *Garcia*, 385 F.3d at 966. Because "'*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed,'" the *Garcia* court found that, absent a finding by "the *FDA itself*" that it was defrauded, subsection (a) was preempted. *Id.* (italics in original) (citation omitted). After finding subsection (a) preempted on those facts and relying on the statute's severability provision and basic principles of statutory interpretation, the Sixth Circuit concluded that the statute's non-liability provision applied and affirmed the order granting the defendant summary judgment based on the statute. *Id.* at 966-67. The *Henderson* district court, while not bound by *Garcia*, found *Garcia* well-reasoned and reached the same conclusions. *Henderson*, 2005 WL 2600220, slip op. at *11.

Similarly, in *Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1177 (D. Ariz. 2005), an Arizona statute prohibited punitive damages claims against manufacturers of

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[9] The Michigan statute provides:

> In a product liability action against a manufacturer or a seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the [FDA], and the drug and its labeling were in compliance with the [FDA's] approval at the time the drug left the control of the manufacturer or seller .... This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following: (a) Intentionally withholds from or misrepresents to the [FDA] information concerning the drug that is required to be submitted under the [Federal Food, Drug, and Cosmetic Act], and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted.

Mich. Comp. Laws § 600.2946(5).

FDA-approved drugs. Ariz. Rev. Stat. Ann. § 12-701(A)(1).[10] There again was an exception, subsection (B), under which the statute's prohibition "d[id] not apply" if the plaintiff established that the manufacturer "withheld from or misrepresented to the [FDA] information known to be material and relevant to the harm which the plaintiff allegedly suffered." *Id.* at § 12-701(B).

The *Kobar* court concluded that "the rationale that led the *Buckman* court to find implied preemption applie[d] with equal force" to subsection (B) of the Arizona statute. *Kobar*, 378 F. Supp. 2d at 1173. "Both a common law fraud-on-the-FDA claim and an immunity statute that requires a plaintiff to prove fraud on the FDA in order to collect punitive damages place state courts ... in the uncomfortable and difficult position of having to answer the question of what role, if any, the allegedly withheld information would have played in the FDA's complicated approval process." *Id.* Relying on statutory interpretation principles (and despite the apparent absence of a severability provision in the statute), *Kobar* applied the statutory bar against punitive damages and granted partial summary judgment on that basis. *Id.* at 1176-77.

Here, TCPRC § 82.007(b)(1)'s provision for rebutting § 82.007(a)'s presumption, like the exceptions to the Michigan and Arizona statutes at issue in *Garcia*, *Henderson*, and *Kobar*, requires proving a fraud-on-the-FDA claim. Permitting that rebuttal would

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[10] The Arizona statute provides:

> A. The manufacturer or seller of a drug is not liable for exemplary or punitive damages if the drug alleged to cause the harm ... (1) [w]as manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the [FDA] under the [FDCA] or the public health service act ...
>
> B. Subsection A does not apply if the plaintiff proves, by clear and convincing evidence, that the defendant, either before or after making the drug available for public use, knowingly, in violation of applicable [FDA] regulations, withheld from or misrepresented to the administration information known to be material and relevant to the harm which the plaintiff allegedly suffered.

Ariz. Rev. Stat. Ann. § 12-701.

place the fact-finder "in the uncomfortable and difficult position of having to answer the question of what role, if any, the allegedly withheld information would have played in the FDA's complicated approval process." *Kobar*, 378 F. Supp. 2d at 1173. Also, it "would ... cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, w[ould] later be judged insufficient in state court" and create the "sort of litigation [that] would exert an extraneous pull on the scheme established by Congress." *Buckman*, 531 U.S. at 351, 353. Thus, TCPRC § 82.007(b)(1) is preempted where, as here, the FDA has not found that it was defrauded.

Further, TCPRC § 82.007(a)'s presumption of no liability applies even though § 82.007(b)(1) is preempted. The bill that included TCPRC § 82.007 has a severability provision providing that any invalid parts of the statute should not affect the validity of other, valid parts. 2003 Tex. Gen. Laws 204, § 23.03.[11] Moreover, Texas has a general severability statute that makes that the general rule of statutory construction. Tex. Gov't Code § 312.013.[12] Accordingly, the legislature intended the provisions to be severable.

TCPRC § 82.007(a) also satisfies the test for applying a statute after severing its unenforceable parts: "'If, when we strike the statute's [unconstitutional] application ... , we are left with something which "remains complete in itself, and capable of being executed in accordance with the legislative intent, wholly independent of that which was rejected, it must stand."'" *Horizon/CMS Healthcare Corp. v. Auld*, 34 S.W.3d 887, 902 (Tex. 2000) (citations omitted). TCPRC § 82.007(a) "remains complete in itself" and can

[11] 2003 Tex. Gen. Laws 204, § 23.03 ("[i]f any provision of this Act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this Act that can be given effect without the invalid provision or application, and to this end the provisions of this Act are declared to be severable").

[12] Tex. Gov't Code § 312.013 ("if any provision of a statute or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the statute that can be given effect without the invalid provision or application, and to this end the provisions of the statute are severable").

be "executed in accordance with legislative intent" without the particular application of § 82.007(b)(1) plaintiff contemplates because there are four ways to rebut § 82.007(a)'s presumption other than § 82.007(b)(1). *See* TCPRC § 82.007(b)(2)-(5).

Further, TCPRC § 82.007(b)(1) is preempted only in part because it is not preempted when the FDA itself concludes it was defrauded (which has not happened here). Both the *Garcia* and *Kobar* courts, applying similar severability standards to similar statutes, concluded that the remaining, non-preempted portions of the statutes should be given effect. *Garcia*, 385 F.3d at 967; *Kobar*, 378 F. Supp. 2d at 1177. This Court should reach the same result.

b. Plaintiff cannot make the showing TCPRC § 82.007(b)(1) requires.

Even if TCPRC § 82.007(b)(1) were not preempted on these facts (and it is), that provision requires plaintiff to show that Wyeth "withheld from or misrepresented to the [FDA] required information that was material and relevant to the performance of the product and was causally relating to the claimant's injury" to rebut TCPRC § 82.007(a)'s no liability presumption. Plaintiff has not made, and cannot make, that showing. Thus, TCPRC § 82.007(a)'s presumption of no liability bars plaintiff's warnings-based claims.

B. Plaintiff's Warranty Claims Should Be Dismissed For Lack Of A Sale Or An Express Warranty.

Plaintiff's complaint asserts breach of express and implied warranty claims. (Complaint at ¶ 19). But Martin Ackermann took Effexor from one free sample pack that Wyeth left without charge at Dr. Sonn's offices and that Dr. Sonn in turn provided to Mr. Ackermann without charge. The lack of a purchase or sale of Effexor anywhere in the chain of events at issue here mandates dismissing all of plaintiff's warranty claims.

Plaintiff's express warranty claims fail for the additional reason that Wyeth did not make any suicide-related express warranties to Dr. Sonn or Martin Ackermann.

1. Plaintiff's Express and Implied Warranty Claims Fail For Lack Of A Sale.

"The Texas U.C.C. applies to transactions 'in goods.'" *Propulsion Tech., Inc. v. Attwood Corp.*, 369 F.3d 896, 900 (5th Cir. 2004) (footnotes and citations omitted); *see* Tex. Bus. & Com. Code § 2.102. Under the Texas U.C.C., "seller[s]" may extend warranties with "contract[s] for sale" or "sale[s]" that involve "the passing of title from the seller to the buyer for a price." Tex. Bus. & Com. Code §§ 2.102, 2.103(a)(1), 2.103(a)(4), 2.106(a), 2.314-16.[13]

Although they do not uniformly require privity, breach of warranty claims always "require[] an underlying 'sale'" and fail when "there is no sale" by the defendant. *Sanchez v. Liggett & Myers, Inc.*, 187 F.3d 486, 491 (5th Cir. 1999) (applying Texas U.C.C. in product liability action; affirming dismissal of breach of warranty claims against trade association) (citation omitted); *accord Allgood v. R.J. Reynolds Tobacco Co.*, 80 F.3d 168, 170 (5th Cir. 1996) (same). Consistent with the Texas U.C.C.'s express language, courts applying that statute have routinely rejected breach of warranty claims against defendants that did not sell the products that allegedly injured plaintiffs.

For example, the plaintiff in *Allen v. Ortho Pharmaceuticals Corp.*, 387 F. Supp. 364 (S.D. Tex. 1974), had, as here, taken a drug only from a free sample pack. Plaintiff

[13] The Texas U.C.C. defines a "Buyer" as "a person who buys or contracts to buy goods" and a "Seller" as "a person who sells or contracts to sell goods." Tex. Bus. & Com. Code § 2.103(a)(1), (4). It defines a "sale" as "the passing of title *from the seller to the buyer for a price*." *Id.* at § 2.106(a) (emphasis added). With respect to warranties, it provides for (1) express warranties based on "[a]ny affirmation of fact or promise made *by the seller to the buyer* which relates to the goods;" (2) implied warranties of merchantability "in a *contract for ... sale if the seller* is a merchant;" and (3) implied warranties of fitness for purpose "[w]here *the seller* ... has reason to know any particular purpose for which the goods are required and that the *buyer* is relying on the *seller's* skill and judgment." *Id.* at §§ 2.313-15 (emphasis added).

nonetheless sought to assert breach of warranty claims against a defendant pharmaceutical manufacturer. The *Allen* court found "[i]t ... axiomatic that, in order for Article 2 of the Texas Business and Commerce Code to apply, it is necessary that a sale form the basis for the cause of action." *Id.* at 367. Because the plaintiff had obtained the drugs only from a free sample pack, "it [wa]s clear that no sale existed to make Article 2 of the Texas Business and Commerce Code applicable in this instance." *Id.* Accordingly, the court dismissed the warranty claims.

Similarly, in *Olivas v. American Home Products Corp.*, No. EP-02-CA-0311, 2002 U.S. Dist. LEXIS 26024 (W.D. Tex. Oct. 18, 2002), the plaintiff sought to assert breach of warranty claims against Advocare, which did not manufacture or sell the non-prescription drugs that allegedly injured the plaintiff. No warranty claims could be asserted against that defendant: "For there to be an implied warranty of merchantability, there must be a contract for the sale of goods between the seller and the buyer." *Id.*, slip op. at *11 (*citing* Tex. Bus. & Com. Code § 2.314).

Likewise, in *Gulf Coast Regional Mental Health-Mental Retardation Center v. McLenna*, No. 01-86-0108-CV, 1986 Tex. App. LEXIS 8161 (Tex. App. - Houston [1st Dist.] Aug. 7, 1986, no writ), the plaintiff sought to assert breach of warranty claims relating to a boat he received as a gift. The *Gulf Coast* court dismissed those claims because the defendant "did not engage in a 'sale' of the boat, and therefore, he was not a seller within the definition of [Tex. Bus. & Com. Code] § 2.106(a)." *Id.*, slip op. at *4.

Here, Martin Ackermann took all seven Effexor pills from a single, free sample pack that a Wyeth sales representative "left" in Dr. Sonn's offices. (Sonn Dep. at 112:3-5 (Ex. C) ("Q. Is it correct that you gave him one and only one sample package? A.

Right."); *id.* at 191:17-22 ("Q. So is the probable sequence of events, Dr. Sonn, that a Wyeth drug rep came to your office ... and then left sample packs ... ? A. That's ... right.")).[14] The pack was marked "Sample - Not For Sale." (Effexor Pack Pictures at 3, 5 (Ex. I) (pictures of Martin Ackermann's Effexor blister and sample packs)).

Given that neither Martin Ackermann nor Dr. Sonn purchased that free sample pack, there was no "buyer," Wyeth was not a "seller," and there was no "sale" because there was no "passing of title from the *seller* to the *buyer for a price*." Tex. Bus. & Com. Code §2.103(1), (4), § 2.106(a) (emphasis added). Because "[u]nder Texas law only actual sellers are liable for breach of warranty," *Allgood*, 80 F.3d at 170, plaintiff's breach of warranty claims fail.

2. No Evidence Supports Plaintiff's Express Warranty Claim.

An express warranty claims requires, among other things, the defendant to make an express warranty. *See* Tex. Bus. & Com. Code § 2.313(a)(1). Absent evidence of a warranty, summary judgment is required. *E.g.*, *Gerber v. Hoffmann-La Roche Inc.*, 392 F. Supp. 2d 907, 923 (S.D. Tex. 2005) (dismissing express warranty claim against pharmaceutical manufacturer for lack of proof of express warranty).

Here, plaintiff has not identified and cannot identify any suicide-related express warranty that Wyeth extended to Martin Ackermann or Dr. Sonn. Tellingly, her response to Wyeth's interrogatory seeking information about any express warranties that Wyeth purportedly extended to Martin Ackermann identified no express warranties at all and, instead, focused solely on implied warranties. (Pl's Resp. to Int. No. 23 (Ex. O)).

[14] Rozlyn Ackermann's testimony and plaintiff's interrogatory responses confirm Dr. Sonn's testimony. (R. Ackermann Dep. at 98:25 - 99:10 (Ex. E) ("Q. The only Effexor you ever got in the whole world was this one blister pack? A. That is correct."); Pl's Resp. Int. No. 8 (Ex. F) ("Dr. Sonn provided professional samples.")). Moreover, the pharmacy record does not list Effexor. (CVS Pharmacy Record (Ex. B)).

In addition, Dr. Sonn testified that he reviewed the Effexor package insert as reproduced in the *Physicians' Desk Reference*. (Sonn Dep. at 42:11 - 43:25 (Ex. C); *see also* 2002 *Physicians' Desk Reference* (Ex. N)). That insert included, among other things, an express "Suicide" precaution that patients taking the drug should be "[c]lose[ly] supervised" due to the "possibility of suicide attempt." (6/5/01 Effexor XR Package Insert at 6 (Ex. G)). Further, Martin Ackermann "did not seem to have read anything or know anything about Effexor" before Dr. Sonn prescribed it, and Dr. Sonn did not remember a Wyeth representative calling on him before Martin Ackermann's suicide. (Sonn Dep. at 110:9-11, 196:7-11 (Ex. C)).

Similarly, Rozlyn Ackermann relied on Dr. Sonn to select Effexor and knew of no suicide-related express warranties that Wyeth made to Martin Ackermann:

> Q. Did you rely on Dr. Sonn to select the antidepressant to be used?
>
> A. Unfortunately, yes.
>
> Q. And you had never heard of Effexor before, ha[d] you?
>
> A. Never.
>
> Q. You had not seen any advertisements for it?
>
> A. No....
>
> Q. You did not rely ... on any advertising or statements that you had heard about that Wyeth made about this drug?
>
> A. No, because at that point I hadn't heard of any statements.

(R. Ackermann Dep. at 147:18 - 148:9 (Ex. E)).[15] Accordingly, the express warranty claims fail because Wyeth gave Martin Ackermann no suicide-related express warranty.

[15] Rozlyn Ackermann also testified that (a) she did not read Effexor's package insert; and (b) the Ackermanns did not retain a copy. (R. Ackermann Dep. at 145:24 - 146:14 (Ex. E) ("Q. And you never read the Effexor package insert, did you? ... A. I don't believe I did. Q. [Y]ou were relying on Dr. Sonn to give you the information you needed with respect to Effexor? A. And also the box. I did read the box.

C. Plaintiff's DTPA Claims Should Be Dismissed For Lack Of A "Consumer" And Because The Claims Do Not Survive Death.

Plaintiff's complaint seeks to pursue remedies for the alleged breaches of express and implied warranties not only under warranty law, but also under the Texas Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. & Com. Code §§ 17.41 *et seq.* (Complaint at ¶ 19). Plaintiff's DTPA claims fail for multiple reasons. Initially, plaintiff's only alleged DTPA violations are supposed breaches of warranty. (Complaint at ¶ 19). Because those breach of warranty claims fail, her DTPA claims based on them also fail. Further, and as discussed below, plaintiff's DTPA claims also fail (a) for lack of a DTPA "consumer" because Martin Ackermann never purchased or sought to purchase Effexor; and (b) because DTPA claims do not survive death.

1. Martin Ackermann Was Not A DTPA "Consumer" Because He Did Not Purchase Or Seek To Purchase Effexor.

Plaintiff's DTPA claims fail because Martin Ackermann was not a "consumer" under the DTPA. "The [Texas] Legislature did not intend the DTPA for everybody. It limited DTPA complaints to 'consumers.'" *PPG Indus., Inc. v. JMB/Houston Ctrs. Partners Ltd. P'ship*, 146 S.W.3d 79, 85 (Tex. 2004) (footnote omitted). A "consumer" under the DTPA is "an individual ... who seeks or acquires by purchase or lease, any goods or services," and the DTPA defines both "goods" and "services" as chattels or services "purchased or leased for use." Tex. Bus. & Com. Code § 17.45(1), (2), (4) (emphasis added). "Whether a party is a consumer under the DTPA is a question of law." *Rayford v. Maselli*, 73 S.W.3d 410, 411 (Tex. App. - Houston [1st Dist.] 2002, no pet.) (citations omitted).

(continued...)
Marty may have read this; I did not.... Q. And when you found the Effexor starter pack and blister pack this [the package insert] wasn't with it, was it? A. No. If it was, I would have probably kept it.")).

Courts are "bound to construe these terms in accordance with their statutory definitions," and persons who "do not seek to purchase or lease" goods or services are not "consumers" and cannot assert DTPA claims. *Transport Ins. Co. v. Faircloth*, 898 S.W.2d 269, 274 (Tex. 1995) (citation omitted). Thus, the Texas Supreme Court in *Transport Insurance* found that a third party negotiating with an insurance company to settle an insurance claim did "not seek to purchase or lease any of the services of the insurer" and, therefore, could not assert claims under the DTPA because she was "not a 'consumer.'" 898 S.W.2d at 274.

Courts routinely have found that, while DTPA "consumers" need not have finalized or consummated the purchase or lease transaction and need not have made the purchase directly from the DTPA defendant,[16] they must have at least sought to "purchase or lease" the goods or services that gave rise to the claim. *E.g., Meineke Disc. Muffler v. Jaynes*, 999 F.2d 120, 125 (5th Cir. 1993) (franchisee was not "consumer" with respect to Texas DTPA claims concerning franchisor's trademark ownership rights that "formed the basis of the DTPA claims"). For example, the court in *Angeles v. Brownsville Valley Regional Medical Center, Inc.*, 960 S.W.2d 854 (Tex. App. - Corpus Christi 1997, pet. denied), found that, when a hospital gratuitously agreed to dispose of a stillborn fetus and the parents were not asked to pay for that service, the parents were not DTPA "consumers." Similarly, the court in *Bass v. Hendrix*, 931 F. Supp. 523, 535-36 (S.D. Tex. 1996), found that therapy workshop participants who did not pay for the

[16] *See, e.g., Arthur Andersen & Co. v. Perry Equip. Corp.*, 945 S.W.2d 812 (Tex. 1997) (purchaser of corporation could bring DTPA claim based upon faulty audit against auditor although the seller, rather than the purchaser, paid for the audit); *Sherman Simon Enters., Inc. v. Lorac Serv. Corp.*, 724 S.W.2d 13 (Tex. 1987) (employer could bring DTPA claim against car rental agency although car rental agency failed to submit agreed-upon lease charge for payment); *Kennedy v. Sale*, 689 S.W.2d 890 (Tex. 1985) (employee could bring DTPA claim for misrepresentations in connection with insurance policy when employer purchased the policy); *Cameron v. Terrell & Garrett, Inc.*, 618 S.W.2d 535 (Tex. 1981) (home purchasers could bring DTPA claim against real estate agent who represented home seller).

workshop were not DTPA "consumers" because "[a] gratuitous act is not a purchase under the DTPA."[17]

Here, all of Martin Ackermann's Effexor came from a free sample pack labeled outside and inside "Sample - Not For Sale." (Sonn Dep. at 112:3-5; 191-17-22 (Ex. C); R. Ackermann Dep. at 98:25-99:10 (Ex. E); Effexor Pack Pictures at 3, 5 (Ex. I) (pictures of the sample and blister packs); *see also* CVS Pharmacy Record (Ex. B) (Effexor not listed in pharmacy record)). Martin Ackermann neither purchased nor sought to purchase Effexor. Because he did not "seek[] or acquire[]" Effexor "by purchase or lease," he was not a "consumer" under the DTPA, and his DTPA claims fail under the rule that "limit[s] DTPA complaints to 'consumers.'" *PPG Indus.*, 146 S.W.3d at 85 (footnote omitted).

2. DTPA Claims Do Not Survive Death.

If any DTPA claims ever existed here (and they did not), they did not survive Martin Ackermann's death. At common law, personal or punitive actions do not survive death. *State Farm Fire & Cas. Co. v. Gandy*, 925 S.W.2d 696, 706 (Tex. 1996) (at common law, "[c]auses of action ... for personal torts did not survive the plaintiff's death and could not be assigned"). Neither the DTPA nor the Texas survival statute provides that DTPA claims survive death. *See* Tex. Bus. & Com. Code §§ 17.41 *et seq.* (DTPA); TCPRC § 71.021 (survival statute). Both federal and state courts have found that,

[17] *Accord Mosk v. Thomas*, No. 14-02-01130-CV, 2003 Tex. App. LEXIS 10311, slip op. at *11 (Tex. App. - Houston [14th Dist.] Dec. 4, 2003, no pet.) (husband who obtained property in divorce settlement was not a DTPA "consumer" vis-à-vis his ex-wife); *Rayford v. Maselli*, 73 S.W.3d 410, 411 (Tex. App. - Houston [1st Dist.] 2002, no pet.) (inmate receiving gratuitous legal services was not a DTPA "consumer"); *LaRue v. Genescreen, Inc.*, 957 S.W.2d 958, 961 (Tex. App. - Beaumont 1997, pet. denied) (criminal suspect whose DNA was improperly tested by genetic testing laboratory retained by the State of Texas was not a DTPA "consumer"); *Roberts v. Burkett*, 802 S.W.2d 42, 47 (Tex. App. - Corpus Christi 1990, no writ) (borrower who received gratuitous legal services was not a DTPA "consumer"); *March v. Thiery*, 729 S.W.2d 889, 896 (Tex. App. - Corpus Christi 1987, no writ) (children who inherited home were not DTPA "consumers" with respect to home seller); *Rutherford v. Whataburger, Inc.*, 601 S.W.2d 441, 444-45 (Tex. Civ. App. - Dallas 1980, writ ref'd n.r.e.) (winner of promotional contest that did not require purchase was not a DTPA "consumer"); *Hall v. Bean*, 582 S.W.2d 263, 265 (Tex. Civ. App. - Beaumont 1979, no writ) (winner of boat race was not DTPA "consumer").

because DTPA claims are personal claims that did not survive at common law, and there is no statutory provision providing otherwise, DTPA claims do not survive death. *E.g.*, *Kirby v. B.I. Inc.*, No. 4:98-CV-1136-Y, 2003 U.S. Dist. LEXIS 16964, slip op. at *45-46 (N.D. Tex. Sept. 26, 2003) (DTPA claims do not survive death); *Lukasik v. San Antonio Blue Haven Pools*, 21 S.W.3d 394, 402 (Tex. App. - San Antonio 2000, no pet.) (same); *but see Thomes v. Porter*, 761 S.W.2d 592, 594 (Tex. App. - Fort Worth 1988, no writ) (DTPA claims do survive death).[18]

Indeed, while the Texas Supreme Court declined to decide this issue in *PPG Industries*,[19] its determination there that DTPA claims may not be assigned due to their "personal and punitive nature" supports the decisions finding that DTPA claims do not survive death. *PPG Indus.*, 146 S.W.3d at 92. Accordingly, plaintiff's DTPA claims fail for this reason as well.

D. Plaintiff's Fraud And Misrepresentation Claims Should Be Dismissed For Lack Of A Misrepresentation Or Reliance.

Plaintiff asserts misrepresentation claims based on strict liability, negligence, and fraud. (Complaint at ¶¶ 17, 18, 20). Whatever the underlying legal theory, however, misrepresentation claims require a showing that the injury was caused by justifiable reliance on the defendant's misrepresentation. *See, e.g.*, **Strict Liability**: *Crocker v. Winthrop Labs.*, 514 S.W.2d 429, 431 (Tex. 1974) (strict liability misrepresentation claim

[18] *Compare Mendoza v. American Nat'l Ins.*, 932 S.W.2d 605, 609 (Tex. App. - San Antonio 1996, no writ) (DTPA claims do not survive death), *and First Nat'l Bank v. Hackworth*, 673 S.W.2d 218, 221 (Tex. App. - San Antonio 1984, no writ) (en banc) (same), *with Mahan Volkswagen, Inc. v. Hall*, 648 S.W.2d 324, 333 (Tex. App. - Houston [1st Dist.] 1982, writ ref'd n.r.e.) (DTPA claims survive death).

[19] *PPG Indus., Inc. v. JMB/Houston Ctrs. Partners Ltd. P'ship*, 146 S.W.3d 79, 91, 91 n.58 (Tex. 2004) ("we do not decide whether DTPA claims survive to a consumer's heirs, a related but sometimes distinct inquiry" from the question there of whether DTPA claims may be assigned); *see also Plumley v. Landmark Chevrolet*, 122 F.3d 308, 311 (5th Cir. 1997) (noting that intermediate Texas appellate courts were divided over whether Texas DTPA claims survive death); *Shell Oil Co. v. Chapman*, 682 S.W.2d 257, 258 (Tex. 1984) ("reserv[ing] to another day discussion of survival of DPTA damages").

provides for "'liability for physical harm ... caused by justifiable reliance upon the misrepresentation'") (*quoting Restatement (Second) of Torts* § 402B); **Negligence:** *Federal Land Bank Ass'n v. Sloane*, 825 S.W.2d 439, 442 (Tex. 1991) (negligent misrepresentation claim requires showing that "plaintiff suffer[ed] pecuniary loss by justifiably relying on the representation"); **Fraud:** *Ernst & Young, L.L.P. v. Pacific Mut. Life Ins. Co.*, 51 S.W.3d 573, 577 (Tex. 2001) (fraud claim requires showing that plaintiff "actually and justifiably relied upon the representation and thereby suffered injury").

Here, plaintiff's misrepresentation claims fail because, just as Wyeth never extended a suicide-related express warranty (*see* pages 24 to 26 above), Wyeth never made (and Dr. Sonn or Martin Ackermann never relied on) any suicide-related misrepresentations. Thus, the Court should dismiss plaintiff's misrepresentation claims.

V. CONCLUSION

The Court should grant Wyeth's state-law motion for summary judgment.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the forgoing document has been filed electronically on the 23rd day of June, 2006, and is available for viewing and downloading from the Eastern District of Texas ECF system. Notice of Electronic Case Filing has been sent automatically to all parties listed below and in the ECT Case service List in effect on the date of electronic filing, which constitutes service of same, and satisfies the requirements of Fed. R. CIV. P. 5(b)(2)(D).

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